Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Budget Estimates 2015-16, 1 - 2 June 2015

Ref No: SQ15-000650

OUTCOME: 7 – Health Infrastructure, Regulation, Safety and Quality

Topic: Medical Device Approval

Type of Question: Hansard Page 62, 2 June 2015

Senator: Xenophon, Nick

Question:

1. There are thousands of devices approved for use in Australia.
   a) Should the TGA be more prescriptive about those approved for use?

Answer:

1. a)
There are currently more than 48,000 entries for medical devices included in the Australian Register to Therapeutic Goods (ARTG). The Therapeutic Goods Administration has no legal power to limit the number of applications made for inclusion of medical devices in the ARTG. Medical devices included in the ARTG are required to comply with standardised criteria for quality, safety and performance under the Therapeutic Goods legislation. The regulatory processes are designed to maintain high minimum standards of quality, safety and performance while maintaining the regulatory burden as low as possible commensurate with product risk.